

REMARKS

The Official Action dated July 20, 2005, has been carefully considered. Accordingly, the changes presented herein, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

In the Official Action, the Examiner objected to claim 30 as being drawing to an invention nonelected with traverse. The objection is traversed, as claim 30 is cancelled by present amendment. Reconsideration is respectfully requested.

The Examiner rejected claims 28, 29, 31-35, and 39-44 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that there was no basis in the original disclosure for the limitation in claim 28 that the side which includes the apertures is a "leading" side. The rejection is traversed. The original disclosure at paragraphs 00013-00015 describe the process of separating the layers of the corneal epithelium as including sliding the epithelial separator or cannula along under the corneal surface in one direction (i.e., away from the hinge region). See Figs. 1c, 1d. The edge of the spatula-like member away from the hinge region is, inherently, the leading edge. However, claim 28 has been amended to state that the apertures are located along one side of the spatula-like member, and the "leading" edge terminology has been removed. Support for this amendment is found in paragraph 20 (which describes apertures as being disposed on one lateral surface relative to a contact surface and an upper surface) and Figures 8-13. Accordingly, the rejection with regard to claims 28, 29, 31-35, and 39-44 is traversed and reconsideration is respectfully requested.

The Examiner rejected claims 28, 31, 32, 34, 35, 42 and 43 under 35 USC 102(e) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as being obvious over, Yaacobi, et al. (U.S. Pat. No. 6,413,245). The Examiner asserted that Yaacobi discloses a

connecting end, spatula-like member including an arcuate distal shape, a side having a plurality of apertures which is inherently a "leading side", and inherently capable of ejecting fluid onto the cornea.

The rejection is traversed. Claim 35 has been canceled. By present amendment, claim 28 has been amended to state that the radius of curvature of the spatula-like member is substantially equal to a radius of curvature of a cornea of the a human eye, and the apertures are located along one side of said spatula-like member. Claim 28 has further been amended to remove the reference to ejecting fluid onto the cornea, and to recite the adaption of the instrument to eject fluid to separate epithelium layers within the cornea. The instrument of Yaacobi is described as a cannula used to deliver drugs into Tenon's capsule of the eye, and the radius of the curvature of the cannula thereby of necessity being substantially equal to the radius of curvature of a human eye. The radius of curvature of the Yaacobi instrument is designed to insure that the instrument does not penetrate the sclera or the periocular tissues (see col. 5, lines 58-63). As the present instrument is designed to be inserted between corneal layers, the radius of curvature of the instrument of the present invention must be compatible with the radius of curvature of the cornea, which is inherently smaller than the radius of curvature of the human eye. While Yaacobi describes the radius of curvature of the drug delivery cannula as being varied, this variation is to match the radius of curvature of the eye of adults with larger or smaller eyes, or pediatric patients with smaller eyes. The radius of curvature of the cornea of such patients would be correspondingly smaller as well. Accordingly, the radius of curvature of the Yaacobi cannula, in order to be used for its described purpose as a sub-Tenon drug delivery device for a patient, must be substantially equal to the radius of curvature of the eye of the patient, and could not have a radius of curvature equal to the cornea.

In addition, Applicant finds no suggestion or teaching of using the Yaacobi cannula by inserting it between two epithelium layers of the cornea to cause them to separate. In fact, due to its size and configuration, Applicant does not believe that the Yaacobi cannula could be so used. The instrument of Yaacobi is described solely as a drug delivery or drug deposit instrument. As claim 28 as amended is now in allowable form, claims 31, 32, 34, 35, 42 and 43 also are now allowable in present form. Accordingly, the rejection with regard to claims 28, 31, 32, 34, 35, 42 and 43 is traversed and reconsideration is respectfully requested.

The Examiner rejected claims 33 and 39-41 under 35 USC 103(a) as being unpatentable over Yaacobi, et al. The Examiner stated that Yaacobi failed to disclose the specific claimed dimensions and numbers of apertures, but that it would have been obvious to use the specific claimed dimensions and number of apertures.

The rejection is traversed. Claims 33 and 39-41 are dependent on independent claim 28. As discussed above, claim 28 as amended is now in allowable form. Accordingly, claims 33 and 39-41 also are now in allowable form. Accordingly, the rejection with regard to claims 33 and 39-41 is traversed and reconsideration is respectfully requested.

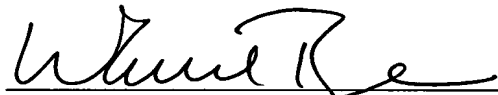
The Examiner rejected claims 29 and 44 under 35 USC 103(a) as being unpatentable over Yaacobi in view of Doshi, et al. (U.S. Pat. No. 6,443,944). Yaacobi does not disclose a spatula-like member having a trapezoidal shape. The Examiner asserted that it would have been obvious to combine the tubular member of Doshi having a trapezoidal shape with the instrument of Yaacobi, apparently since each shape would work equally well.

The rejection is traversed. Claims 29 and 44 are dependent on independent claim 28. As discussed above, claim 28 as amended is now in allowable form. Accordingly, claims 29 and 44 also are now in allowable form. Further, Applicant finds no suggestion or teaching in Doshi to deliver a fluid through the tube. Instead, the tube of Doshi is used to contain the mechanism by which the manipulating arms are controlled inside the body. It would not have

been obvious to combine the tube of Doshi, used to contain a mechanism for manipulating arms inside the body, with a cannula used to deliver fluids behind the Tenon's capsule of the eye. Accordingly, the rejection with regard to claims 29 and 44 is traversed and reconsideration is respectfully requested.

Accordingly, the rejections of claims 28-29, 31-35 and 39-44 have been traversed, and reconsideration is respectfully requested. It is believed that the above represents a complete response to the rejections under 35 U.S.C. 112, 102(e) and 103(a), and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



W. Edward Ramage, Reg. No. 50,810
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC
Commerce Center, Suite 1000
211 Commerce Street
Nashville, Tennessee 37201
(615) 726-5771